REMARKS

The Office Action mailed on December 18, 2009 has been reviewed and the comments of the Examiner carefully considered. Claims 1, 3-7, 9-13, and 19 are pending and currently stand rejected. Claim 1 has been amended herein. No new matter has been added by way of this amendment.

Rejection under 35 U.S.C. § 112, First Paragraph – Written Description

Claims 1, 3-7, 9-13 and 19 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description for recitation of the value "1%" wound healing therapeutic substance.

While Applicants do not agree with the rejection itself, nor the grounds for the rejection, and respectfully contend that no new matter was added by way of the previous amendments, Applicants have amended the claim to recite "about 0.01% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance." The Examiner acknowledged in the office action that the range "about 0.01% to about 5%" is explicitly supported in the specification. Applicants submit that the "new matter" rejection therefore does not apply, and request reconsideration and withdrawal of the rejection.

Rejection under 35 U.S.C. § 112, Second Paragraph - Indefiniteness

Claims 1, 3-7 and 9-13 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for recitation of the phrase "about at least 1% to about 5%".

While not in agreement with the basis for the Examiner's rejection, but in an attempt to advance prosecution of the claims, Applicants have amended claim 1 (from which claims 3-7 and 9-13 depend) to remove the language "at least". This amendment is supported throughout the specification, and for example, in the paragraph spanning the bottom of page 5 and the top of page 6.

The Examiner also alleges that the term "about 0.01%" encompasses the value of "zero". Applicants respectfully disagree, and contend that the claim as written does not encompass "zero percent" of a wound healing therapeutic substance.

First, claim 1 necessarily comprises "at least one wound healing therapeutic substance". It would be contradictory for the term "about 0.01%" to be construed to encompass zero wound healing therapeutic substance. The claim affirmatively claims the inclusion of a wound healing therapeutic substance, and reading the term "about 0.01%" to encompass zero wound healing therapeutic substance would be beyond the scope of the claim.

Second, Applicants note that in the originally filed claims, prior to any amendment, claim 8 referred to the affirmative inclusion of at least one wound healing therapeutic substance. By way of a previous amendment, the subject matter of claim 8 was incorporated into claim 1. The doctrine of claim differentiation requires that original claims 1 and 8 be interpreted as distinct, and therefore, that the subject matter of claim 8 should be interpreted to affirmatively include an amount of wound healing therapeutic substance (i.e., to include an amount great than zero).

Finally, Applicants note that MPEP § 2173.05(b) sets forth that "In determining the range encompassed by the term "about", one must consider the context of the term as it is used in the specification and claims of the application." Citing *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326, 81 USPQ2d 1427, 1432 (Fed. Cir. 2007). As Applicants have set forth above, the use of the term "about 0.01%", in the context of the pending claims, requires the claims to be interpreted to include an amount of wound healing therapeutic substance greater than zero. Furthermore, as an additional distinction between the term "about 0.01%" and the value "zero", Applicants direct the Examiner's attention to page 5 of the specification, lines 13 and 26, which specifically identify examples of "zero percent" of a particular component. In other words, the specification makes a clear distinction between zero percent (the "absence" of a substance), and an amount greater than zero, such as "about 0.01%".

Accordingly, Applicants respectfully submit that the indefiniteness rejection has been either overcome or does not apply, and request reconsideration and withdrawal of the rejection.

Rejection under 35 U.S.C. § 102(e)

Claims 1, 3-7, 9, 12 and 19 were rejected under 35 U.S.C. § 102(e) as anticipated by Guo et al. (US 7,252,837). Regarding independent claim 1, the Examiner alleged that Guo et al. "teaches a wound dressing composition comprising an intimate mixture of a chitosan and an oxidized cellulose (see Example 4)". Applicants respectfully traverse the rejection and submit that the claims are not anticipated for the following reasons.

It is well-settled that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990) and also MPEP § 2131 (quoting *Verdegaal Bros. v. Union Oil C. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). "The identical invention must be shown in as complete detail as is contained in the ...claim" Id. (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, Guo must describe each and every element of the claims in order to anticipate these claims under section 102(b). However, Guo does not meet this burden.

Guo et al. does not disclose a wound dressing composition comprising an intimate mixture of a chitosan, an oxidized cellulose, and from about at least 0.01% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance, the cited reference does not suggest, much less teach, the present invention. In particular, Guo does not teach the inclusion of any wound healing therapeutic substance whatsoever. As set forth above in detail, the pending claims do not encompass "zero percent" wound healing therapeutic substance.

Anticipation exists only when the cited reference discloses all the elements, features, or limitations. *Carella v. Starlight Archery and Pro Line Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986). Thus, "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). Consequently, Applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(e). Further,

applicants submit that claims 3-7, 9, 12 and 19 are thereby allowable as written as depending from an allowable independent claim.

Rejections under 35 U.S.C. § 103(a)

Claims 1, 3-7, 9-13, and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cullen et al. (WO 00/33893). Regarding independent claim 1, the Examiner alleges that Cullen et al. renders the claims obvious because Cullen teaches 0.00001% to 1% therapeutically effective peptide. Applicants respectfully traverse the rejection and submit that the pending claims are not obvious in view of Cullen et al. for the following reasons.

While not in agreement with the ground for rejection, but in an attempt to advance prosecution of the claims, Applicants have amended claim 1, without prejudice to the inclusion of the cancelled subject matter in one or more continuing or divisional applications, to recite specific wound healing therapeutic substances. In particular, Applicants have amended claim 1 to encompass wound healing therapeutic substances selected from the group consisting of non-steroidal anti-inflammatory drugs, steroids, local anesthetics, and antimicrobial agents. This amendment is supported throughout the specification, and for example, in the paragraph spanning the bottom of page 5 and the top of page 6.

As set forth in the specification, non-steroidal anti-inflammatory drugs include acetaminophen. Antimicrobial agents may, for example, comprise an antiseptic, an antibiotic, or mixtures thereof, and in particular, may include tetracycline, penicillins, terramycins, erythromycin, bacitracin, neomycin, polymycin B, mupirocin, clindamycin and mixtures thereof. Antiseptics include, but are not limited to, silver, including colloidal silver, silver salts including salts of one or more of the anionic polymers making up the material, silver sulfadiazine, chlorhexidine, povidone iodine, triclosan, sucralfate, quaternary ammonium salts and mixtures thereof.

Cullen et al. does not teach any of the above wound healing therapeutic substances. Cullen et al. teaches only therapeutic peptides and growth factors. As amended, claim 1 does not encompass wound healing therapeutic agents that are therapeutic peptides or growth factors.

Accordingly, there is no teaching or suggestion in Cullen et al. of the presently-claimed invention.

The test which must be met for a reference or a combination of references to establish obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part, the proper test for obviousness:

Office policy is to follow *Graham* v. *John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. 103 ...

> [T]he four factual inquires enunciated therein as a background for determining obviousness are as follows:
> (A) Determining the scope and contents of the prior art;
> (B) Ascertaining the differences between the prior art and the claims in issue;
> (C) Resolving the level of ordinary skill in the pertinent art; and
> (D) Evaluating evidence of secondary considerations. (MPEP § 2141)

When applying 35 U.S.C. § 103, the following tenets of patent law must be followed: 1) the claimed invention must be considered as a whole; 2) the references must be considered as a whole; 3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and 4) reasonable expectation of success is the standard with which obviousness is determined (MPEP § 2141 II).

Cullen et al. does not provide any teaching or suggestion for the skilled artisan to make or use a wound dressing composition comprising an intimate mixture of a chitosan, an oxidized cellulose, and having from about at least 0.01% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance selected from the group consisting of a non-steroidal anti-inflammatory drug, a steroid, a local anesthetic, and an antimicrobial agent. Nor does Cullen et al. provide any motivation to the skilled artisan to arrive at such a composition having those particular levels of individual components. Cullen et al. does not teach or suggest any advantage or necessity to do so.

As Cullen et al. does not provide any suggestion or motivation for the skilled artisan to make or use a wound dressing composition comprising an intimate mixture of a chitosan, an oxidized cellulose, and with from about at least 0.01% to about 5% by weight on a dry weight

basis of at least one wound healing therapeutic substance selected from the group consisting of a non-steroidal anti-inflammatory drug, a steroid, a local anesthetic, and an antimicrobial agent, Cullen et al. does not suggest, much less teach, the present invention, and therefore does not provide the skilled artisan with any reasonable expectation of success in arriving at the presently-pending claims.

Consequently, applicants respectfully request reconsideration and withdrawal of the rejection of claim 1, 3-7, 9-13, and 19 under 35 U.S.C. § 103(a).

Double Patenting Rejection

Claims 1, 3-7, and 9-12 were rejected on the ground of nonstatutory obviousness-type patenting over U.S. Patent No. 7,252,837. Applicants respectfully submit this rejection is does not apply, and request withdrawal thereof, for the following reasons.

The Examiner acknowledges that the '837 patent does not encompass a wound healing therapeutic substance (see page 16 of the present Office Action). As set forth above herein in detail, the pending claims do not encompass "zero percent" wound healing therapeutic substance, but rather, encompass amounts of at least one wound healing therapeutic substance greater than zero percent.

As the '837 patent does not provide any suggestion or motivation for the skilled artisan to make or use a wound dressing composition from about at least 0.01% to about 5% by weight on a dry weight basis of at least one wound healing therapeutic substance selected from the group consisting of a non-steroidal anti-inflammatory drug, a steroid, a local anesthetic, and an antimicrobial agent, the '837 patent does not suggest, much less teach, the present claims, and therefore does not provide the skilled artisan with any reasonable expectation of success in arriving at the presently-pending claims. Applicants therefore request reconsideration and withdrawal of the double patenting rejection, as the rejection does not apply.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5089 to clarify any unresolved issues raised by this response.

The Director is hereby authorized to charge the fee for the Petition for Extension of Time as well as charge/credit Deposit Account No. **50-0310** (Billing No. 088888-0105) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

BREDA M. CULLEN ET AL.

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By: _____

Thomas M. Sossong Jr.
Registration No. **48,463**
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: (215) 963-5809
Facsimile: (215) 963-5001
E-Mail: tsossong@morganlewis.com